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Date of Deposit: August 18, 2005

Jean C. Lee

Attorney Docket No.: 11000.1004c3
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of **Annette Lasham & James D. Watson**

Group Art Unit: 1635

Application No.	:	10/028,415
Filed	:	December 20, 2001
For	:	**METHODS FOR MODULATING APOPTOTIC CELL DEATH**
Examiner	:	Tracy Vivlemore

DECLARATION OF DR. ANNETTE LASHAM

MAILSTOP: AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

The undersigned, Dr. Annette Lasham, hereby declares:

1. I am a Senior Investigator at Genesis Research and Development Corporation Limited, the assignee of the subject patent application, and an inventor of the subject matter disclosed and claimed in the present patent application. I have a PhD. in Molecular Neurobiology and have been working in the field of molecular biology for 14 years. I am an author on 11 published papers.

2. Ohga et al. (*Cancer Res.* 1996, 56:4224-4228) describe studies in which a construct including almost full-length antisense YB-1 was introduced into a human epidermoid cell line, referred to as KB, in order to establish two stable cell lines having reduced concentrations of YB-1. Ohga et al state that the level of YB-1 was different between the two cell lines. These cell lines were then shown to have increased sensitivity to various DNA-damaging agents or drugs.

Considered 3/3/06 TV

During generation of the stable cell lines, only cells which had incorporated the antisense YB-1 plasmid DNA plus antibiotic marker into the genome would have survived, as cells lacking the antibiotic marker would necessarily have been killed. It is known that reduction of YB-1 causes death of cells having wild-type p53 (see, for example, Example 4, page 30, line 17 - page 35, line 3, of the instant specification; and Lasham et al., *J. Biol. Chem.* 2003, 278:35516-23). Accordingly, only those cells having a compromised p53 pathway could have survived the antibiotic selection procedure employed by Ohga et al. Indeed, if cell death had occurred, there would have been little or no cells remaining for Ohga et al. to employ in their subsequent analysis of sensitivity to different drugs. I thus believe that the KB cell lines employed by Ohga et al. must have a compromised p53 apoptosis pathway.

3. The undersigned further declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements, and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 35 of the United States Code.

Annette Lasham, Ph.D.

10 August 2005
Date